Drug Testing Advisory Board

Open Session

March 9, 2005

Agenda Item: Welcome, Opening Remarks.

MR. STEPHENSON (Chair): Good morning. I would like to convene the open session of the Drug Testing Advisory Board. There will be an opportunity for members of the public to make comments before the end of the session. If you have not already done so, make sure that you let a member of my staff know your intentions. I have three individuals at this time who have indicated they want to make a public comment. We will make sure that there is enough time for this to happen.

In this open session, this is a part of a process that we are using to deal with the business of the Drug Testing Advisory Board. Unfortunately, at this point in time, much of the business of the Board is in closed session because we are formulating proposed final rules and procedures that need to be discussed. Until they are not only discussed, but have been reviewed legally and procedurally and distributed for comments and input from a number of other parts of HHS, as well as other parts of the Federal government, they are not public and they are not final.

This is the time when we wrestle with not only the science, but the wording and the process of working through the negotiations of areas of common interest and so on. It is not that we are not working. Trust me, we are. It is just that to the public, you are not seeing it right now until the process is complete. This is the mechanism that we have been instructed to use by legal council. It is a process that is standard for these kinds of activities.

By necessity, this is an abbreviated session. Be careful what you wish for with long open sessions, because those will come soon enough as we begin a process of being able to distribute and share some of the other things that come after the final clearance of these rules, because everything from implementation and process and quality assurance checks and everything else that must come with it will certainly become a part of the grist for the mill for public discussions.

Agenda Item: HHS Update.

DR. BUSH (HHS): I attended the American Academy of Forensic Sciences meeting that was held a couple of weeks ago in New Orleans. It is a venue where not just forensic toxicologists gather together, but all other disciplines of forensic sciences. There was a nice session there concerning drug testing of oral fluid. People are looking at what we do in the context of the Federal drug testing program, and people around the world are looking at these alternative technologies. There are roadside breath alcohol and DUID, driving under the influence of drugs programs all around the world, and everyone is using similar kinds of technologies, wanting similar endpoints, similar evaluation/interpretation of results.

We fit into that, and as the Board, as Federal employees, and members of the public all have interests in it.

We took the opportunity to present, upon request, some information about the oral fluids and our pilot PT program. You all have seen this information before as it has been released and presented bit by bit, point by point, cycle by cycle by John Mitchell from Research Triangle Institute, who has done a great job with it. We consolidated all of that, and actually it was a very good presentation. We are not prepared to make a presentation on that here, but it is a good summary and it works well for us. Again, that is something that is going on behind the scenes that you do not really see that was a good presentation in another arena, but very beneficial for us as we move forward in writing the final guidelines.

As Bob said, we are busy. I liken us to ducks on a pond. They look so stoic and so nice and placid on the surface, but they are paddling like mad underneath the water. That is the situation we are in right now.

I would also like to welcome you to our new building and our new facilities here. This is the first time we have convened a meeting here, and I hope you enjoy this new facility. We are very proud and happy to have this. We moved in at the end of August. Thanks for joining us here. We will be having many meetings here in the future, as well as other venues, as we always have had in the past.

Bob spoke very well and clearly about why we have these short open sessions, so I will not belabor that anymore.

Agenda Item: DOT Update.

MR. ELLIS (DOT): I do appreciate the opportunity to be here today. I'm with the Office of Drug and Alcohol Policy and Compliance in the Office of the Secretary of Transportation. I'm here representing our director, John Bobo. He asked me to give you his greetings, as well as the greetings of Secretary Mineta. We continue to be very grateful for the invitation from HHS to attend the DTAB meetings. These are very important to us to be able to observe.

We certainly, as the Department of Transportation, do clearly rely on HHS for not only the laboratory certification handled by their very capable contractors, RTI, but we also rely on HHS for the establishment of our cutoffs, which drugs we are testing for, and also those scientific and technical issues which help us affirm the scientific soundness and legal defensibility of the test results that are generated on our employees.

As most of you are aware, the Department does regulate the testing of over approximately 12 million regulated employees, and we believe we have somewhere over 600,000 employers who are subject to the various regulations of our operating administrations. Our particular office, as you are also aware, are really the stewards of a regulation known as 49 CFR Part 40, which establishes the criteria on how, when the operating administrations dictate, the testing must be done. Our regulation determines how specimens are to be collected, the laboratory process, medical review officer process, and finally the return to work process through a function called the substance abuse professional.

Our jobs, besides being the stewards of Part 40, are also to assist our operating

administrations with their implementation of their regulations, to partner with them, and also to provide them guidance associated with the testing of their regulated employees. We also have other responsibilities related to liaisons with the White House, with foreign governments, and with other Federal agencies as well.

In terms of updating you, we want to remind you we have a website which is going great guns. It is www.dot.gov/ost/dapc/, and we are very proud of it. We get approximately 14,000 to 20,000 hits per month. It contains not only our regulations, as well as frequently asked questions, as well as interpretations, but it also contains links to all the other DOT agency rules. It is a great asset. It also gives you an opportunity to get to us. There is a portion that gives you not only our contact phone numbers in the office but also the contact phone numbers of all the DOT agencies, and we have also linked with our colleagues at Homeland Security and the U.S. Coast Guard because they still use our 49 CFR Part 40 as part of their testing program as well. The website is a great place to be. It also gives you an opportunity to sign up to be contacted by us anytime there is something new in the Department of Transportation drug and alcohol testing arena. Please use it. It generates approximately 500 to 600 contacts per month from medical review officers, other service agents, as well as members of the public who have questions about our program.

Other things that are going on for us right now is that we expect our Notice of Proposed Rulemaking on urine specimen validity testing to be released this spring. We are working very hard on it, and it also requires a lot of work coordinating the NPRM with our various operating administrations. They obviously have an important say in how the Notice of Proposed Rulemaking will be constructed.

When that is released, all of you will have the opportunity to provide comments. We are looking forward to everyone's comments. They are going to be very important as we craft our final regulations on urine specimen validity.

Thank you.

Agenda Item: NRC Update.

MR. McCUNE (NRC): I bring you greetings from the NRC commissioners. This is a very important body to us at the NRC as well. As you know, in the government and in general, HHS does such a fine job of science and background, the mission of the DTAB certainly supporting that, to give all of us a scientific basis to go forward with what we need to do in terms of drug and alcohol testing and control.

I will tell you about where we are in the NRC with our drug and alcohol policy. During DTAB meeting in December, I mentioned that our 10 CFR Part 26 is being revised. It is currently in the headquarter's concurrence process at the NRC. In fact, tomorrow is the milestone to have all office concurrences back. We see no issues with any of the offices including our Office of General Counsel. As you may know in the private sector as well the government, sometimes the Office of General Counsel is the most discerning with respect to this type of policy.

The schedule is to have the draft rule to the commissioners in June 2005. We

expect that in the fall that draft rule will be put out for public comment, and as with our DOT friends, all of you will have the opportunity to comment on that. The scope really of 10 CFR Part 26 are the licensees and other entities in the NRC. So it is not quite as broad as some of our other policies in the Federal government, certainly our DOT friends, who apply to a much larger population. However, there are some significant positions that are covered by these policies, reactor operators and security forces who employ deadly force, just to name a few.

But we are hopeful that there will not be any significant issues because we think it is a very good policy. Right now the industry, as well as the headquarters, see no significant issues with the drug and alcohol portions of the rule.

I would also like to thank our SAMHSA friends. I was here on another matter back in the fall and got the opportunity to meet with some other government agencies regarding the methods by which companies are circumventing drug and alcohol testing, and I was provided with some very good briefing materials from our SAMHSA friends. We had a follow-on meeting in the NRC in November of this year where all of our safeguard and security personnel were present, and I stole from that presentation, I will admit, and it was very helpful to our safeguard and security directors all over the NRC to see what kinds of companies and products are out there trying to circumvent drug and alcohol testing.

Along with the policy in the NRC, we also have to do the implementation and the oversight of these programs and knowing what kind of efforts are out there to circumvent the processes is very important to us, and I think SAMHSA will continue to do good work along those lines.

DR. BUSH: Thank you, Tim, and now that I got a little bit of breath back and you gave me a little springboard here, I think I'll take off on that a little bit. We have been gathering a lot of information and data on drug testing specimen adulterant materials, substitution products, cleansing agents, all kinds of different approaches for any and every specimen to be tampered with by a donor to obscure or mask a drug test result.

We have also been spending a lot of time here on that, gathering that information, because we find as we go forward - well, let us flash back a few years. If you go on the World Wide Web, on the Internet, and just type into a favorite search engine - mine happens to be Google; I have no financial interest in it, but I use Google. I just type in "beat a drug test," and you end up with 700,000 hits in two-tenths of a second. A lot of it is good information. A lot of it is very accurate information on how to beat a drug test. A lot of it is misinformation. Nevertheless, there is a lot of chatter and products out there concerning beating a drug test.

That was in the old days when it was just urine drug tests, beating a urine drug test. Now, these websites and the purveyors of these products have definitely gone upscale to meet proposals that we have made for Federal employee drug testing using alternative specimens such as sweat, hair, and oral fluid, and there is just a myriad of products out there. The ingenuity is pretty amazing. So there is a lot of attention being paid to these because as we are developing our final guidelines for the future, we need to take a look at all of this and evaluate the efficacy of these products and how do we approach this.

How do we approach specimen validity testing as a whole? How do these

products impact the test results? Quite honestly, at the American Academy of Forensic Sciences, there were several presentations concerning just that, people finding the most ingenious of ways, novel ways to try to beat a drug test, some successful, some not, some physically harmful to the specimen donor who tries these very ingenious ways to get over on the drug test. But nevertheless, we have to look at this because we have to evaluate the efficacy of the drug testing program. How do we make sure that the goal of the program is met? If the goal is to detect and deter drug use, we must make sure that we can do that with what procedures we put into place and the methods we use. That is something else we have been doing and will become also part of the final guideline package.

MR. STEPHENSON: The issues around adulterant are ones that have certainly created a marketplace for some of the products, but in the process of creating the marketing material and the claims that have been made, it has certainly sparked a sense of outrage by Congress, by U.S. attorneys in various parts of the country, and by the DEA. The issues that we have had to deal with of necessity over the last several years are not of our choosing. I would far prefer that we did not have to do this, that this was not a part of our culture, that when you pose a challenge to someone to provide a clean specimen to determine whether or not they have misused drugs, that they will willfully continue to use those drugs and at the same time try to mask and lie about and try to avoid being detected.

The best way to beat a drug test is to get the message that we are not ever going to give up, that we're always going to be looking for the products and the processes, and that even if it is a small part of a percentage of the total number, because of the raw numbers, the whole, real numbers that are affecting public security, whether it is security forces employing deadly force potentially, whether it is individuals in the Federal agencies that have guns and badges or national security clearances, whether it is others that have public safety concerns, we have that responsibility, and we are stubborn, which means that we are going to always continue to press detection and counter surveillance approaches and so forth.

Having said that, there are a lot of these products that do not work, and that is one of the biggest things we have learned. By far, the great majority of these things do not work at all, and the only marketing approach that is done is to the gullible person who tries in desperation to continue a lifestyle that misuses illegal substances and then thinks that they can be gotten out of this at the last second by taking some kind of drink or taking some kind of pill or masking it in some other way. Almost in every case, we were able to detect and to quantify the presence of an adulterant that is added, and in the case of things that are added to the human body and allowed to process inside the human being, most of them do not have any kind of intended effect such that it would be helpful to that person to avoid detection.

My belief is that if you really want to have an opportunity for a good job, that you simply do not misuse drugs, that that is one of the decisions that you make as an individual who is either going into an employment arena or is in one and you like the job you have and do not want to lose it. Choose not to use the drugs. This is an easy thing to do, and most of us can rationalize almost any activity that we take in life. But in this circumstance, it is one that does take on a responsibility that we cannot sidestep. We have to maintain the surveillance and

process.

As we continue with this process to deal with adulterant issues, there will likely be an introduction of legislation, there will certainly be continued seizures of products and of websites and putting up the bad examples of the market approach that we have in this country of those who continue to try to sell these kinds of products. That is just the dynamic that is now set up.

But we are still committed as an agency to use every opportunity to provide good prevention information to people, to provide educational information, and for those that have a problem, to have them step forward and seek treatment that is appropriate and effective. Once they have gone through treatment to deal with relapse prevention and restoring them into the community, family life and so on, that is our whole vision for the agency, a place in the community for everyone. Although you can abhor the behavior, you do not disrespect the individual. That is a part of the process that we need to do better at as a society, and I think we can, and I think that that is a part of the process that this board and this group plays.

We hold people accountable for their behavior and we hold them responsible for making sure that they do provide the proper kinds of evidence that they are in fact not misusing illegal drugs if they carry a special charter, if they have a special responsibility in our society. The courts have already said it is an appropriate balance between privacy and the need for public safety, and that is where we are these days.

I am through pontificating, but it is a part of the philosophy that is embedded in each one of us, and it is a very heavy responsibility that we all carry, and we all recognize it.

Agenda Item: Public Comments.

MS. VARLOTTA: Mr. Stephenson, all members of the Drug Testing Advisory Board, allow me to introduce myself again. My name is N.B. Varlotta, and I am a career flight attendant with an excellent employment history. In March of 1999 my employer terminated me only one month shy of my providing 20 years of faithful service. I was falsely accused of substituting a drug screen sample under the standards established by this board.

I continue to take my time and time from my family to travel across country in order to attend these meetings because I am passionate about this board's involvement in validity testing. Ladies and gentlemen, indulge your imagination for just a few moments. Imagine you are out of work due to a downsizing or recalled by the military to report for service to our country. A job interview is under way and you now are subject to a drug screen test. This test is no problem because drug use is not a part of your life. But guess what? You receive a call from the medical review officer indicating that you have failed the drug test.

Unbeknownst to you, the failing is the validity test which is attached to drug testing. You may or may not have medical insurance at this time, to further complicate the issue. A life- and career-altering accusation has been made despite your lack of any drug use. You do not have a clue of what, why, or how creatinine, pH, or nitrites have to do with your future or continued employment. What is in place for this worker to exonerate themself, other than the medical review officer requesting medical history?

I believe this board has created the potential for a business, company, corporation or military to eliminate a present or future worker who has possibly a high-cost medical problem such as HIV or lupus, cancer or kidney disease, with a false accusation and validity testing attached to drug testing.

I am again asking this board to discontinue the so-called validity testing immediately. Failing such action, since careers can continue to be threatened, and since the science continues to be questionable, and in view of the fact that human error can still never be removed from this equation, I would persist in suggesting that it is incumbent on this board to adopt specific step-by-step procedures acceptable to all employers and military which would allow a worker to clear their name with a remedy in the event of a false accusation.

Due process is still a fundamental right in this country. Where is the due process in validity testing? Let's not forget those still trapped in the quagmire left behind by the original guidelines, and let us not create a new generation of falsely accused. Life, liberty, and the pursuit of happiness in our country should be the goal. False accusations created by unproven validity testing undermine our inalienable rights.

Thank you for your time. Do you have any questions?

MR. STEPHENSON: Thank you very much for your public comments. I think you gave a written copy to the reporter?

MS. VARLOTTA: Yes, I did.

MR. STEPHENSON: All right. Thank you.

MS. VARLOTTA: Thank you.

MR. STEPHENSON: Next?

MR. DRAKE: Good morning. My name is Richard Drake. When I was 50 years old, after 35 years of service, I was drug tested. The airline, Delta Air Lines, that tested me falsified and adjusted, with the help of the laboratories, the results of my test. The use of whiteout was determined. I am now 62 years old and three months ago I was awarded $2.5 million in a settlement with Delta by jury's award for the outrageous violations of the rules and regulations that you people have established that allowed them to do exactly what they did.

To use Ms. Bush's words, "ingenious" is the way that Delta Air Lines and the laboratories that were involved in this have fought for 12 years not to say that these things did not happen, not to say that I was guilty of drug use or adulterating my urine sample, but they fought to keep me out of court to prevent me from ever having any rights at all to bring my question and to bring my proof of what happened to a court. They continue on today. The laboratories today are still fighting me in the Court of Appeals not to say that these things did not happen, but to say I have no right to be in court or to bring any action against them for the violations they clearly committed.

To use Mr. Stephenson's words which he just spoke, "we hold people responsible for their behavior." This board works very hard to hold these people responsible for their behavior. They fight me to prove that they do not have a responsibility for their behavior, and they fight me today in court, as does the DOT and the FAA. They fight not to say these things did not happen and they are responsible for their actions, but to keep people, the employees that are tested, from ever bringing any action against them for their deeds, for their misdeeds.

Five years ago I presented you with a report from Kenneth Mead, the Inspector General of the DOT, who was forced to finally investigate my case by Congressman Wolfe, and they wrote a report. As the final statements in that report, after discovering, yes, there were violations and that, yes, I did not have any avenue to go after these people who have committed them, the DOT Inspector General said that the current regulations under 49 Part 40 be reviewed and appropriate revisions explored to avoid transportation industry employees the right to private action against employers who violate federal drug testing procedures resulting in disciplinary actions against employees.

I brought that to you five years ago. You have done absolutely nothing. You say that this is not your responsibility. This report from the DOT Inspector General is telling you, the only sitting board that deals with these regulations, to do this, to fix this. Mr. Stephenson, Ms. Bush, Mr. Vogl have all told me, well, we have nothing to do with that, we only set up things to do with forensic testing and the chemicals and the scientific part of it. That is absolutely untrue. You are the people that set up 49 Part 40, and Mr. Stephenson just got finished saying that we want to make sure that these regulations do hold the people responsible for what they do.

You are only talking about the employees, the employees who have no representative on this board, but the laboratories do have representatives on this board. Three of the people that are being sought in my court cases sit on this board and prevent me from bringing this case to court, continuously. We are now in the Court of Appeals on that very question. Where is the DOT regulation that Mr. Mead said would be done five years ago? They refuse to do it, and you helped them.

You should be ashamed of yourselves. You set these things up for a good purpose, to keep drugs and drug use people out of the public sector that has to do with safety. You do that because it's a good thing, and yet you say but geez, don't look at the things we do when we violate the rules that we create ourselves.

Do it. Take the responsibility that's put on this board that Mr. Mead said you had. You fix the 49 Part 40 to include the right of the people that are being tested to go after those who violate the rules. You have destroyed the lives of people. We have the young lady up in Colorado who fought very hard to have her case heard. She lost her home, she lost her car. Her children had to drop out of college because she couldn't afford to keep them in anymore, and you did nothing, not because she was trying to prove that she didn't do what she did, which she clearly did. Three tests. This young lady does not produce creatinine. Three observed tests, three separate laboratories. She does not create creatinine, and she lost her job because of it.

She proved it. She just doesn't do that. Did you help? Did anybody here give

her any assistance? Did the DOT jump up and help her? No. Today that young lady's life is destroyed. Today she's out there with a ruined life still, and not because she couldn't prove that she was right but because there was no avenue, and still is not avenue, for her to prove she was right.

I thank you for your efforts in trying to keep drugs out of the public safety area, but I think you people are very much like the Nazis during the war when you are the people who created the gas chambers and said, well, we don't decide who goes in, we don't have anything to do with that. We don't decide what happens with them. We just design them. Well, you're designing the gas chambers, it's being abused, and you have a responsibility to straighten out what happens to the people.

Thank you.

MR. STEPHENSON: At this time I'm going to refrain from any further comments except to suggest that if there are areas of interest that some members of our group might have, that you talk during the break, that perhaps there be some exchange of information to correct the misstatements and apprehensions that have been presented, especially for the Department of Transportation rules, regulations and procedures. I think it is long overdue.

MR. EDGELL: I am Ken Edgell. I am with American Medical Review Officers and Pipeline Testing Consortium. Since November 2004, specimen validity testing has been mandated for all laboratories. It is a difficult process to determine the specimen validity capabilities of the laboratories when it comes to adulterant testing. An employer can find an HHS-certified laboratory by referring to the monthly Federal Register listing of currently certified laboratories. However, that listing provides no information on laboratory SVT capabilities.

Our employers do not believe that it is the responsibility of the employer to have to call each laboratory to find out what they do or don't do. They believe that it is the responsibility of HHS to gather that information and display it for the employer. Laboratory capabilities would fit perfectly in a chart generated, of course, by HHS and provided in the Federal Register monthly. HHS determines whether a laboratory is certified, and part of their process is to evaluate their ability to do what they claim they can do, plus you, HHS, could keep up with changes better.

In calling laboratories, I have found that some have changed their approach to adulterant testing in the past few months, preferring to dump out invalid results rather than identify the adulterant. Employers need to know what adulterants can be detected and who can detect them. Some employers want to take a more aggressive testing approach than others. Sometimes marketing material for such a complex subject as SVT might not be as accurate as it should be. For this reason and the reasons above, determining a laboratory's SVT capability should be left to those who award the certification, not those who use the services.

Thank you.

MR. STEPHENSON: Thank you very much. At this time, I would ask if there are any other public comments from the audience. (No response.)

At this time I will close the open session of the Drug Testing Advisory Board. I really appreciate your time and effort here in the public session. I know it is a commitment for some of you to come here for a short period of time. We have a continued following and interest. Some occasions are briefer than others, but in this case, trust me, we are not going to visit Washington, D.C., today. We are going to stay in this room until the late hours of the afternoon and tomorrow and have a very aggressive discussion dealing with a number of issues and legal reviews.

For members of the public, there will be an opportunity for discussions after we close this session.

Open session was adjourned at 9:13 a.m.